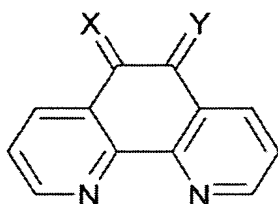


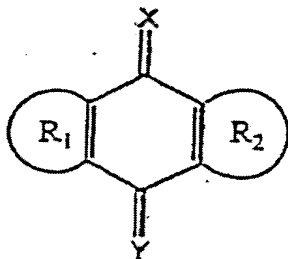
## REMARKS

Claims 1-5, 7-11, 18, 20-25, and 27-29 remain in the application. Claims 1 and 18 have been amended. Claims 16, 17, 19, and 26 have been cancelled. Reconsideration of this application, as amended, is respectfully requested.

Claim 1 has been rewritten to specify that the mediator consists of a compound having the following formula:



where X and Y are independently oxygen, sulphur,  $\text{CR}^3\text{R}^4$ ,  $\text{NR}^3$ , or  $\text{NR}^3\text{R}^4$  or the functional group  $\text{CZ}^1\text{Z}^2$ , where  $\text{Z}^1$  and  $\text{Z}^2$  are electron withdrawing groups; and  $\text{R}^3$  and  $\text{R}^4$  are independently a hydrogen atom, a hydroxyl group or a substituted or unsubstituted alkyl, aryl, heteroaryl, amino, alkoxyl, or aryloxyl group, wherein said active electrode is formulated with filler and binder ingredients. Claim 18 has been amended to specify that the mediator consists of a compound having the following formula:



where X and Y are independently oxygen, sulphur,  $\text{CR}^3\text{R}^4$ ,  $\text{NR}^3$ , or  $\text{NR}^3\text{R}^4$  or the functional group  $\text{CZ}^1\text{Z}^2$ , where  $\text{Z}^1$  and  $\text{Z}^2$  are electron withdrawing groups;  $\text{R}_1$  and  $\text{R}_2$  are independently heteroaromatic groups; and  $\text{R}^3$  and  $\text{R}^4$  are independently a hydrogen atom, a hydroxyl group or a substituted or unsubstituted alkyl, aryl,

heteroaryl, amino, alkoxy, or aryloxy group, wherein said active electrode is formulated with filler and binder ingredients. Support for these changes finds authority in In re Wertheim, 191 USPQ 90 (CCPA) 1976) at 97, wherein it is stated:

.....That what appellants claim as patentable to them is *less* than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. As we said in a different context in In re Saunders, 58 CCPA 1316, 1327, 44 F. 2d 599, 607, 170 USPQ 213, 220 (1971):

To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed. Cf. In re Ruff, 45 CCPA 1037, 1049, 256 F. 2d 590, 597, 188 USPQ 340, 347 (1958). Since the patent law provides for the amendment during prosecution of *claims*, as well as the specification supporting claims 35 USC 132, it is clear that the reference to “particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention” in the second paragraph of 35 USC 112 does not prohibit the applicant from changing what he “regards as the invention” (i.e., the subject matter on which he seeks patent protection) during the pendency of his application.....

Claims 5, 6, and 24 have been amended to correct typographical errors in the expression NAD(P)<sup>+</sup>, which was incorrectly typed as NAD(P)<sup>-</sup>. Support for this change can be found at page 12, lines 1-6 of the specification.

Because the foregoing amendment touches the merits of the application, a showing under 37 C.F.R. 1.116(c) is expected. The amendment is necessary to overcome the rejections based on the newly cited reference Gorton et al., U. S. Patent No. 4,940,464. The amendment was not earlier presented because the

Examiner had not yet relied on the Gorton et al. to reject any of the claims of the application. The undersigned was unaware of the Gorton et al. reference until he reviewed the file in order to prepare the amendment mailed on June 27, 2003. The present amendment is being presented at this time because the claims, if amended as proposed, would avoid the rejections based on 35 U.S.C. § 103, and thus the amendment would place the case in condition for allowance or in better condition for appeal. The claims, if amended as proposed, would avoid the rejection on the references. In view of the foregoing reasons, the Examiner has sufficient grounds for entering the amendment.

Claims 22 and 23 were rejected under 35 U. S. C. §112, second paragraph, being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 has been amended to address this ground of rejection.

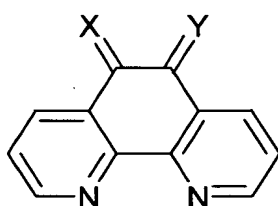
Claims 1-3 stand rejected under 35 U. S. C. §103(a) as being unpatentable over Hedenmo et al. (Analyst, 1996, vol. 121, pp.1891-1895) in view of Carter et al. (USP 5,628,890). This rejection is respectfully traversed/addressed for the following reasons.

Hedenmo et al. (Analyst, 1996, vol. 121, pp.1891-1895) (hereinafter "Hedenmo et al."), discloses the mediator  $\text{Os}(4,4'\text{-dimethyl},2,2'\text{-bipyridine})_2(1,10\text{-phenanthroline-5,6-dione})$  for the catalytic oxidation and recycling of NADH. Reagentless dehydrogenase carbon paste amperometric electrodes for glucose were developed, mixing the mediator, glucose dehydrogenase and  $\text{NAD}^+$  in the paste.

Carter et al., U. S. Patent No. 5,628,890 (hereinafter "Carter et al."), discloses an electrode strip for use in an electrochemical sensor for measuring a compound in a sample, including an electrode support, a reference or counter electrode disposed on the support, a working electrode spaced from the reference or counter electrode on the support, a covering layer defining an enclosed space over the reference and working electrodes and having an aperture for receiving a sample into the enclosed space, and a plurality of mesh layers interposed in the enclosed space between the covering layer and the support, the covering layer having a sample application aperture spaced from said electrodes and said reference electrode spaced from said working electrode at a position remote from and on the opposite side of said working

electrode from said aperture. The working electrode includes an enzyme capable of catalyzing a reaction involving a substrate for the enzyme or a substrate catalytically reactive with an enzyme and a mediator capable of transferring electrons transferred between the enzyme-catalyzed reaction and the working electrode to create a current representative of the activity of the enzyme and representative of the compound.

The electrode strip of claims 1-3 requires that the mediator consist of a compound having the formula:



where X and Y are independently oxygen, sulphur,  $\text{CR}^3\text{R}^4$ ,  $\text{NR}^3$ , or  $\text{NR}^3\text{R}^4$  or the functional group  $\text{CZ}^1\text{Z}^2$ , where  $\text{Z}^1$  and  $\text{Z}^2$  are electron withdrawing groups; and  $\text{R}^3$  and  $\text{R}^4$  are independently a hydrogen atom, a hydroxyl group or a substituted or unsubstituted alkyl, aryl, heteroaryl, amino, alkoxy, or aryloxy group,

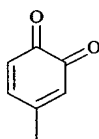
Hedenmo et al. discloses a compound wherein the nitrogen atoms in the heteroaromatic rings are attached to a metal atom to form a complex. As amended, claims 1-3 exclude metals from forming a complex with the nitrogen atoms in the heterocyclic rings of the mediator compound recited in claims 1-3. For this reason, Hedenmo et al., by itself, does not render claims 1-3 obvious to one of ordinary skill in the art.

Carter et al. merely discloses the use of a mediator in general. Carter et al. does not disclose or suggest the use of the compounds recited in claims 1-3 as a mediator for the reaction between nicotinamide cofactor-dependent enzyme and a nicotinamide cofactor. For the foregoing reasons, it is submitted that the combination of Hedenmo et al. and Carter et al. does not render claims 1-3 of this application obvious to one of ordinary skill in the art.

Claims 4, 5, 7-11 stand rejected under 35 U. S. C. §103(a) as being unpatentable over Hedenmo et al. and Carter et al. in further view of Batchelor et al., "AMPEROMETRIC ASSAY FOR THE KETONE BODY 3-HYDROXYBUTYRATE", *Analytica Chimica Acta*, 221 (1989) 289-294. This rejection is respectfully traversed/addressed for the following reasons.

Batchelor et al., "AMPEROMETRIC ASSAY FOR THE KETONE BODY 3-HYDROXYBUTYRATE", *Analytica Chimica Acta*, 221 (1989) 289-294 (hereinafter "Batchelor et al."), discloses a dry-strip electrochemical sensor for the direct measurement of 3-hydroxybutyrate in blood. The sensor utilizes the electrocatalytic oxidation of enzymically generated NADH by the redox mediator 4-methyl-o-quinone. The enzyme 3-hydroxybutyrate dehydrogenase, cofactor NAD<sup>+</sup> and 4-methyl-o-quinone were incorporated into single-use disposable strip electrodes.

Batchelor et al. refers to the use of 4-methyl-o-quinone (4-methyl-1,2-benzoquinone) as a mediator for NADH in the construction of a biosensor electrode for D-3-hydroxybutyrate, which is a ketone. The structure of 4-methyl-o-quinone is:



This mediator is no more suggestive of the mediators recited in claims 4, 5, and 7-11 of this application than are the mediators disclosed in Hedenmo et al. and Carter et al. As stated previously, the claims of this application, as amended, exclude metals from forming a complex with the nitrogen atoms in the heterocyclic rings of the mediator compounds as called for by Hedenmo et al., and neither Carter et al. nor Batchelor et al. discloses or suggests anything that would remedy the deficiency of Hedenmo et al. For the foregoing reasons, it is submitted that the combination of Hedenmo et al., Carter et al., and Batchelor et al. does not render claims 4, 5, 7-11 of this application obvious to one of ordinary skill in the art.

Claims 18, 20, 22-25, 27, and 29 were rejected under 35 U. S. C. § 103(a) as being unpatentable over Hedenmo et al. in view of Gorton et al. (USP 4,490,464) and Carter et al. This rejection is respectfully traversed/addressed for the following reasons.

Gorton et al., U. S. Patent No. 4,940,464 (hereinafter "Gorton et al."), discloses an electrode for the electrochemical regeneration of coenzymes dihydronicotinamide adenine dinucleotide (NADH), dihydronicotinamide adenine dinucleotide phosphate (NADHP), or analogs thereof, characterized in that it comprises carbon or a graphitic material to the surface of which is adsorbed a condensed aromatic ring system comprising phenoxazinium ions, phenoxazinones, phenothiazinium ions or phenothiazinones, substituted or unsubstituted.

As stated previously, the claims of this application, as amended, exclude metals from forming a complex with the nitrogen atoms in the heterocyclic rings of the mediator compounds as called for by Hedenmo et al., and Carter et al. fails to disclose or suggest anything that would remedy the deficiency of Hedenmo et al. Claim 18, as amended, and the claims depending from claim 18, either directly or indirectly, require that  $R_1$  and  $R_2$  be heterocyclic. In Gorton et al., the rings analogous to  $R_1$  and  $R_2$  are carbocyclic. Thus, Gorton et al. fails to disclose or suggest the use of a mediator compound having heterocyclic rings analogous to  $R_1$  and  $R_2$ , as required by the mediator compound recited in claims 18, 20, 22-25, 27, and 29. For these reasons, it is submitted that the combination of Hedenmo et al., Gorton et al., and Carter et al. fails to render claims 18, 20, 22-25, 27, and 29 obvious to one of ordinary skill in the art.

Claims 21 and 28 were rejected under 35 U. S. C. § 103(a) as being unpatentable over Hedenmo et al., Gorton et al., and Carter et al., in further view of Batchelor et al. This rejection is respectfully traversed/addressed for the following reasons.

As stated previously, the claims of this application, as amended, exclude metals from forming a complex with the nitrogen atoms in the heterocyclic rings of the mediator compounds as called for by Hedenmo et al., and neither Carter et al. nor Batchelor et al. discloses or suggests anything that would remedy the deficiency of Hedenmo et al. Claims 21 and 28 require that  $R_1$  and  $R_2$  be heterocyclic. In Gorton et al., the rings analogous to  $R_1$  and  $R_2$  are carbocyclic. Thus, Gorton et al. fails to disclose or suggest the use of a mediator compound having heterocyclic rings analogous to  $R_1$  and  $R_2$ , as required by the mediator compound recited in claims 21 and 28. For these reasons, it is submitted that the combination of Hedenmo et al.,

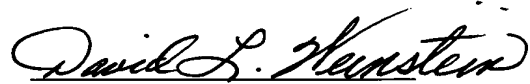
Gorton et al., Carter et al., and Batchelor et al. fails to render claims 21 and 28 obvious to one of ordinary skill in the art.

In view of the foregoing, it is submitted that claims 1-5, 7-11, 18, 20-25, and 27-29 are in condition for allowance, and official Notice of Allowance is respectfully requested.

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